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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,312	11/13/2001	Leroy E. Hood	P - IS 4988	5632

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/30/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/993,312

Applicant(s)

HOOD ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-43, drawn to a method of predicting a behavior of a biochemical system, classified in class 703, subclass 2. If this Group is elected then FOUR of the below summarized specie elections are also required.
- II. Claims 44-48, drawn to a method of identifying functionally interactive components in a biochemical system, classified in class 702, subclass 19. If this Group is elected then TWO of the below summarized specie elections are also required.
- III. Claims 49-56, drawn to a method of identifying a component of a biochemical network via physical interaction map refinement, classified in class 702, subclass 19. If this Group is elected then THREE of the below summarized specie elections are also required.
- IV. Claims 57-63, drawn to a method of identifying a component of a biochemical network via noting changes in a candidate network component due to perturbation, classified in class 702, subclass 19. If this Group is elected then ONE of the below summarized specie election is also required.

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- V. Claims 64-67, drawn to a method of screening for compounds that restore a perturbation state of a biochemical system, classified in class 702, subclass 19. If this Group is elected then ONE of the below summarized specie election is also required.
- VI. Claims 68-74, drawn to a method of diagnosing or prognosing a pathological condition, classified in class 702, subclass 19. If this Group is elected then ONE of the below summarized specie election is also required.

**Specie Election Requirement for Groups I-VI:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group I:

Specie A: a data integration map which is a physical interaction map

Specie B: a data integration map which is not a physical interaction map

For Groups I, V, and VI:

Specie C: a biochemical system which is a cell

Specie D: a biochemical system which is a tissue

Specie E: a biochemical system which is an organism

For Group I:

Specie F: data elements which are in the form of nucleic acid expression

Specie G: data elements which are in the form of protein expression

Specie H: data elements which are in the form of polypeptide-polypeptide interaction

Specie I: data elements which are in the form of nucleic acid-polypeptide interaction

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Specie J: data elements which are in the form of metabolite abundance

Specie K: data elements which are in the form of growth rate

For Group I:

Specie L: a behavior which is a cellular phenotype

Specie M: a behavior which is a biochemical activity

Specie N: a behavior which is an expression level

Specie O: a behavior which is an accumulation level

For Groups II and III:

Specie P: physical interactions which are polypeptide-polypeptide interactions

Specie Q: physical interactions which are polypeptide-nucleic acid interactions

Specie R: physical interactions which are nucleic acid-nucleic acid interactions

For Groups II and III:

Specie S: an expression which involves transcription

Specie T: an expression which involves translation

For Groups III and IV:

Specie U: a component which is a nucleic acid

Specie V: a component which is a polypeptide

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness of a physical interaction map versus a non-physical interaction map (Group I) is because each type of map contains distinct elements (see discussion

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below) with the presence of physical interactions in the aforementioned map that is not found in the latter mentioned map. The distinctness of a cell versus a tissue versus an organism (Groups I, V, and VI) is because the higher level systems contain certain distinct structures and functions not present in the other systems. The distinctness of nucleic acid expression versus protein expression versus polypeptide-polypeptide interaction versus nucleic acid-polypeptide interaction versus metabolite abundance versus growth rate (Group I) is because each data element type contains features and characteristics unique to that element and not required for the other elements. The distinctness of cellular phenotype versus biochemical activity versus expression level versus accumulation level (Group I) is because each is a type of behavior with different characteristics not found in the other behaviors. The distinctness of polypeptide-polypeptide interactions versus polypeptide-nucleic acid interactions versus nucleic acid-nucleic acid interactions (Groups II and III) is because each interaction entails different biochemical mechanisms and properties depending on the involvement of amino acids and/or nucleic acids which are in and of themselves distinct (see discussion below). The distinctness of transcription versus translation (Groups II and III) and nucleic acid versus polypeptide (Group III and IV) is because each specie involves separate chemical and entity types which are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the species are independent and/or distinct invention types for restriction purposes.

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Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different processes, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-VI are directed to processes and methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Group I requires behavior prediction via the identification of correlative changes

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in two data integration maps which is not required by any other group. Group II requires identifying functionally interactive components based on being linked by physical interactions, expression or activity which is not required in any other group. Group III requires identifying components altered due to perturbation of a pathway component via refining the physical interaction map which is not required in any other group. Group IV requires identifying components based on noting changes in candidate network components. Group V is directed to the screening of restoration compounds using test compounds not found in any other group. Group VI involves diagnosing or prognosing a pathological condition which is not found or required in any other group. These distinct processes and methods are often separately characterized and published in literature and would add undue search burden if they were all examined together. Thus, they are considered distinct invention types for restriction purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 22, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER